

Applicants: Presnell et al.

Serial No.: 09/608,918

Filed: June 30, 2000

For: INTERLEUKIN-17 RECEPTOR HOMOLOGUE (As Amended)

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**REMARKS**

Reconsideration and withdrawal of the rejections in light of the above amendments, the accompanying Declaration under 37 C.F.R. §1.132, and following remarks are respectfully requested. Claims 1-20 having been cancelled, claims 21-44 having been added, the pending claims in the above-identified patent application are claims 21-44. No new matter has been added.

**Objection to the Specification**

The Examiner objected to the Title of the Invention as not being descriptive. Applicants have amended the Title thereby rendering the Examiner's objection moot. Withdrawal of the objection is respectfully requested.

The Examiner objected to claim 3 as reciting nonelected sequences (SEQ ID NO:11 and SEQ ID NO:12). Applicants have cancelled claim 3 thereby rendering the Examiner's objection moot. Withdrawal of the objection is respectfully requested.

**Rejection Under 35 U.S.C. §101**

The Examiner rejected claims 1-7 and 17 under 35 U.S.C. §101 as allegedly not being supported by either a specific and substantial credible utility or a well established one. Applicants are proceeding as though this rejection applies to new claims 21-44. In rejecting the claims, the Examiner stated that "[t]he instant invention lacks patentable utility because the claimed effectiveness and functionality of the Zcytor14 are hypothetical" (page 3 of the Office Action). This rejection is respectfully traversed.

In support of a patentable utility, Applicants have submitted a Declaration under 37 C.F.R. §1.132 by Dr. Julia Parrish-Novak. Applicants would like to draw the Examiner's attention to page 70, lines 13-24, which discloses that zcytor14 may play a role in initiating or sustaining inflammation, and that a soluble zcytor14 may be used to inhibit inflammation.

Paragraphs 5 and 6 of the Declaration show that zcytor14 transfected human embryonic kidney 293 cells resulted in IL-17 receptor being significantly up-regulated. Applicants submit it is well-known to one of skill in the art that the IL-17 ligand is a pro-inflammatory cytokine. It is also well-known that IL-17 is able to up-

regulate other pro-inflammatory cytokines, e.g., IL-6 and IL-8, when added to normal human bronchial epithelial (NHBE) cells as shown in paragraphs 7 and 8 of the Declaration. As further evidence of a patentable utility, the addition of a soluble zcytor14 receptor (extracellular domain of SEQ ID NO:2) was able to reduce to background levels the up-regulation of IL-6 (paragraph 9 of the Declaration) and IL-8 (paragraph 10 of the Declaration) caused by the addition of IL-17 in NHBE cells, which endogenously express zcytor14 and IL-17R (paragraph 8). Thus, Applicants submit that one of skill in the art, after reading the specification, claims, and accompanying Declaration, would immediately appreciate at least one tangible use of the present invention that has a real-world benefit, e.g., that zcytor14 (SEQ ID NOs:2 and 10) is able to initiate or sustain inflammation, and that soluble zcytor14 is able to inhibit inflammation. Therefore, Applicants submit that the polypeptides of the present invention have a specific, credible, and substantial real-world use.

Accordingly, reconsideration and withdrawal of the rejection of claims 1-7 and 17 (new claims 21-44) under 35 U.S.C. §101, are respectfully requested.

**Rejections Under 35 U.S.S. §112, First Paragraph**

The Examiner rejected claims 1-7 and 17 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants are proceeding as though this rejection applies to new claims 21-44. This rejection is respectfully traversed.

Applicants respectfully submit that a patentable utility has been established as indicated above, and that one of skill in the art would be able to make and use the invention as claimed (new claims 21-44), as the skilled artisan would be able to readily identify the isolated polypeptides and utilize such by consulting the present specification. Thus, Applicants submit that the metes and bounds of claims 21-44 are well-delineated.

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Accordingly, reconsideration and withdrawal of the rejection of claims 1-7 and 17 (new claims 21-44) under 35 U.S.C. §112, first paragraph, are respectfully requested.

The Examiner rejected claims 1-7 and 17 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants are proceeding as though this rejection applies to new claims 21-44. This rejection is respectfully traversed.

In determining whether an applicant has satisfied the written description requirement, the “fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed.” M.P.E.P. §2163.02. “Such possession is effective if one of ordinary skill in the art could have combined the publication’s description of the invention with his knowledge to make the claimed invention.” Flehmg v. Giesa, 13 USPQ2d 1052, 1055 (B.P.A.I. 1989). The applicant does not have to describe the invention exactly, but it must be clear to one of ordinary skill in the art that the applicant “invented what is claimed.” Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991).

Applicants submit that it would have been clear to one of skill in the art that Applicants were of possession of the claimed invention (new claims 21-44) as of the filing date.

Accordingly, reconsideration and withdrawal of the rejection of claims 1-7 and 17 (new claims 21-44) under 35 U.S.C. §112, first paragraph, are respectfully requested.

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Summary

On the basis of the above amendments and remarks, Applicants believe that each rejection has been addressed and overcome. Reconsideration of the application and its allowance are respectfully requested. If for any reason the Examiner feels that a telephone conference would expedite prosecution of the application, the Examiner is invited to telephone the undersigned at (206) 442-6540.

Respectfully Submitted,



Brian J. Walsh  
Registration No. 45,543

Enclosures:

Petition and Fee for Extension of Time (in duplicate)  
Amendment Fee Transmittal (in duplicate)  
Declaration under 37 CFR §132 with Exhibits A and B  
Postcard

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